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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,810	11/03/2003	Tsuneo Hattori	1828.001US2	4457

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,810	HATTORI ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *102005 & 110303*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicants' preliminary amendments filed 10/20/05 and 11/03/03. With these, Applicants have amended the specification and claims.

Election

2) Acknowledgment is made of Applicants' election filed 10/20/05, without traverse, of invention II, claims 9-17, in response to the restriction requirement mailed 09/20/05.

Status of Claims

3) Claims 1-8 have been canceled via the amendment filed 10/20/05.

Claims 9-17 have been amended via the amendment filed 10/20/05.

Claims 9-17 are pending and are under examination. A First Action on the Merits for these claims is issued.

Information Disclosure Statements

4) Acknowledgment is made of Applicants' Information Disclosure Statements filed 10/20/05 and 11/03/03. The information referred to therein has been considered and a signed copy is attached to this Office Action. The Japanese patent 6-181656 and the French patent 2 606 254 are non-translated documents of foreign languages. Since the Examiner is not versed in these foreign languages, these documents have not been considered and therefore are lined through in the PTO 1449. If Applicants wish the documents to be considered, they may be submitted on a new PTO-1449 accompanied by certified English translations.

Priority

5) The instant application is a continuation of application 09/808,840, filed 03/15/01, *now abandoned*, which claims domestic priority to the provisional application, SN 60/191,211, filed 02/22/2000.

Specification - Informalities

6) The specification is objected to for the following reason(s):

The amendment made to the first paragraph of the specification via the preliminary amendment filed 11/03/03 does not provide the priority information as indicated above in italicized letters under 'Priority'. Amendment to the specification is needed to correct this.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

7) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

8) Claims 9-17 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 9 is vague and indefinite in the recitation 'effective amount' because it is unclear what amount is encompassed in this limitation. The term 'effective' is a relative term which is not specifically defined by the claim. The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the claim. What amount qualifies as an 'effective' amount, and in what capacity the amount is 'effective', i.e., prophylactically effective, therapeutically effective etc., is unclear.

(b) Claims 10-17 lack proper antecedent basis in the limitation: 'A method according to claim ...'. For proper antecedence, it is suggested that Applicants replace the phrase with --The method according to claim ...--.

(c) Claims 9 and 10 are vague, indefinite, confusing and/or inconsistent in scope, because the dependent claim 10 includes the limitation 'the animal or human', whereas the base claim 9 includes the limitation 'animals and humans'. For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the limitation in claim 9 with --an animal or a human--. It is further suggested that Applicants provide proper antecedent basis to the limitation 'human' in line 2 of claim 10 by replacing the limitation with --the human--.

(d) Claim 11 is vague, indefinite and confusing in the recitation: 'method according to claim 9 wherein the immunostimulator is swine plasma albumin-derived peptide', because the immunostimulator recited in claim 9 comprises 'swine plasma'. With regard to the limitation

'the immunostimulator is swine plasma albumin-derived peptide', claim 11 is not further limiting.

(e) Claim 17 is indefinite and confusing in the limitation: 'administered through a route selected from the group consisting of feed, veterinary pharmaceuticals, beverages, food, health food, and pharmaceuticals', because the recited Markush species such as food, beverages etc. do not represent a 'route'. It is suggested that Applicants replace the limitation with -- administered through a feed, veterinary pharmaceuticals, beverages, food, health food, or pharmaceuticals--.

(f) Claim 15 is confusing in the limitation: the immunostimulator is selected from the group consisting of swine plasma, swine plasma mixed with fine-powdered Crustaceae, 'and crust of Crustaceae', because it is unclear how 'the' immunostimulator can be selected from 'crust of Crustaceae'.

(g) Claims 10-16 are vague and indefinite in the limitation 'mg/kg', because it is unclear whether the term 'kg' represents the kg weight of the food or feed administered, or the kg body weight of the animal or the human.

(h) Claims 10-17, which depend directly or indirectly from claim 9, are also rejected as being indefinite because of the vagueness or indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

9) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10) Claims 9-17 are rejected under 35 U.S.C § 102(b) as being anticipated by Suetsuna *et al.* (*Shokuniku ni kansuru Josei Kenkyu Chosa Seika Hokokusho, i.e., Report of the Promotional Research Investigation Results of Edible Means* 10 (1991): 328-334, 1992 - English translated Document of Accession number 930121753 JICST-EPlus – Applicants' IDS).

The page number referred to below represent the page number of the translated document.

It is noted that phagocytic ability (or index) to foreign matter is used as a measure of natural immune function (see Example 1 and first full paragraph on page 13 of the specification).

Suetsuna *et al.* taught a method of significantly increasing the natural killer cell activity of splenocytes and increasing the phagocytosis of opsonized sheep RBCs by alveolar macrophages (i.e., increasing disease resistance) by administering to rats, via food, porcine plasma protein or porcine plasma-derived peptide. The prior art method suggested the presence of immune activating (i.e., immunostimulating) factors in porcine plasma peptide. See abstract; first full paragraph on page 1; and section 2.2. The amount of porcine plasma protein (P) or porcine plasma-derived peptide (PP) contained in the rat cornstarch diet was 15% (see section 2.2 and Table 1). The administration of porcine plasma protein to rats significantly increased the weight of rat thymus and spleen, the organs responsible for natural immunity (see section 3.3, page 8, and last paragraph on page 9). Rats administered with porcine plasma or porcine plasma-derived peptide showed significantly high natural killer activity (see section 3.4, Figure 4, and page 8) and significantly increased phagocytosis of opsonized sheep RBCs (see section 3.6, Figure 5, page 8, and first paragraph on page 10). Furthermore, Suetsuna *et al.* taught the close relationship between the immunity or protection mechanism of the host (i.e., disease resistance) and the nutrition state of the host's living body. Suetsuna *et al.* further taught of the existence of frequent susceptibility to infections and generation and promotion in the progression of cancers in nutritionally abnormal states (see section 4). The porcine plasma-derived peptide was produced by enzymatic digestion of the porcine plasma followed by ultrafiltration, cation exchange chromatography, and gel filtration (see sections 2.1 and 3.1). The presence of albumin in the swine plasma or the porcine plasma-derived peptide is inherent from the teachings of Suetsuna *et al.* since albumin is a known major component of any animal plasma or enzymatically digested plasma. Suetsuna's rat diet product qualifies as a food product, animal feed, or a pharmaceutical. Although Suetsuna *et al.* do not expressly include the dose range limitation of '1-3000 mg/kg', '1-300 mg/kg', '5-100 mg/kg', '30-1000 mg/kg', '70-500 mg/kg', '100-3000 mg/kg' or '200-1200' mg/kg', since the prior art method brought about the same effect of increasing disease resistance, i.e., fortifying bio-defense mechanisms including phagocytic activity towards foreign matter, such as, sheep RBCs, and the enhanced NK cell and

macrophage activity, the prior art method is viewed as inherently including the administration of a dose of '1-3000 mg/kg', '1-300 mg/kg', '5-100 mg/kg', '30-1000 mg/kg', '70-500 mg/kg', '100-3000 mg/kg' or '200-1200' mg/kg' of porcine plasma protein or porcine plasma-derived peptide to the rats included in the study. That the porcine plasma or the porcine plasma-derived peptide used in Suetsuna's method showed significantly greater NK cell activity of splenocytes and significant phagocytic activity towards opsonized sheep red blood cells, and action on alveolar macrophages, indicates the presence of immune activating (i.e., immunostimulating) factors in porcine plasma or porcine plasma peptide, and suggests that the immune-activating porcine plasma or porcine plasma-derived peptide product administered to rats in Suetsuna's method necessarily contained '1-3000 mg/kg', '1-300 mg/kg', '5-100 mg/kg', '30-1000 mg/kg', '70-500 mg/kg', '100-3000 mg/kg' or '200-1200' mg/kg' of porcine plasma protein or porcine plasma-derived peptide. Since the Office does not have the facilities for examining and comparing Applicants' plasma or peptide dose range with the plasma or peptide dose administered to rats in Suetsuna's method, the burden is on the Applicants to show a novel or an unobvious difference between the instantly claimed method and the prior art method. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzerald et al.*, 05 USPQ 594.

Claims 9-17 are anticipated by Suetsuna *et al.*

Objection(s)

11) Claims 10-16 are objected to for not leaving a space between '..00mg/kg'. For clarity, in claims 10-16, it is suggested that Applicants leave a space before the limitation 'mg/kg'.

Remarks

12) Claims 9-17 stand rejected.

13) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The central Fax number for submission of amendments, responses and papers is (571) 273-8300.

14) Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

December, 2005

S. DEVI, PH.D.
PRIMARY EXAMINER